K083383

BIOMÉRIEUX

FEB 18 2009

510(k) SUMMARY

VITEK® 2 Gram Positive Erythromycin for *Streptococcus pneumoniae*

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jolyn Tenllado Associate Staff Regulatory Affairs Specialist
Phone Number:	314 -731-8386
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Date of Preparation:	November 14, 2008

B. Device Name:

Formal/Trade Name:	VITEK® 2 Gram Positive Erythromycin for *Streptococcus pneumoniae*
Classification Name:	Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645
Common Name:	VITEK 2 AST-GP Erythromycin for *Streptococcus pneumoniae*

C. Predicate Device: VITEK 2 Gram Positive Telithromycin for *Streptococcus pneumoniae* (K053186).

D. 510(k) Summary:

A 510(k) for VITEK 2 Gram Positive Erythromycin for *Streptococcus pneumoniae* (K063492) was cleared by FDA on 21Dec2006. This premarket notification is for the same AST with the only modification being a software algorithm change to utilize the existing FDA intermediate breakpoint for Erythromycin and *S. pneumoniae*, and thereby lift the VITEK 2 Systems limitation regarding the inability of the Systems to report intermediate results for Erythromycin and *S. pneumoniae* strains. There has been no change to the VITEK 2 AST-GP Erythromcyin for *S. pneumoniae* formulation since K063492 was cleared. The analysis was modified to conform to standard practice of reporting results for all available FDA breakpoints for an antibiotic/organism combination. The clinical trial data submitted as part of K063492 was re-analyzed using the modified algorithm analysis. There was no new clinical data gathered for this 510(k) notification. The modified algorithm for this AST will be included in a future software release (VITEK 2 Systems software version PC 4.01).

VITEK® 2 Gram Positive Erythromycin for *Streptococcus pneumoniae* is designed for antimicrobial susceptibility testing of *Streptococcus pneumoniae*. It is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. The antimicrobial presented in VITEK 2 AST Cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/ml. The VITEK 2 AST Cards are

essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The bacterial isolate to be tested is diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK 2 System automatically fills, seals and places the card into the incubator/reader. The VITEK 2 Compact has a manual filling and sealing operation. The VITEK 2 monitors the growth of each well in the card over a defined period of time (up to 18 hours). At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antibiotic contained on the card.

VITEK 2 Gram Positive Erythromycin for *Streptococcus pneumoniae* demonstrated substantially equivalent performance when compared with the CLSI broth microdilution reference method, as defined in the FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA, Issued Feb. 5, 2003.

The Premarket Notification (510[k]) presents data in support of VITEK 2 Gram Positive Erythromycin for *Streptococcus pneumoniae*. An external evaluation was conducted with fresh and stock clinical isolates and stock challenge strains. The external evaluations were designed to confirm the acceptability of VITEK 2 Gram Positive Erythromycin for *Streptococcus pneumoniae* by comparing its performance with the CLSI broth microdilution reference method. The data is representative of performance on both the VITEK 2 and VITEK 2 Compact instrument platforms, as evidenced in the AST equivalency study presented in the VITEK 2 Compact 510(k), K050002. VITEK 2 Gram Positive Erythromycin for *Streptococcus pneumoniae* demonstrated acceptable performance of 98.4% overall Category Agreement. Reproducibility and Quality Control demonstrated acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 8 2009

Ms. Jolyn Tenllado
Associate Staff Regulatory Affairs Specialist
bioMérieux
595 Anglum Road
Hazelwood, MO 63042

Re: k083383
Trade/Device Name: VITEK® 2 Gram Positive Erythromycin (≤ 0.25 - ≥ 1 µg/ml)
Regulation Number: 21 CFR § 866.1645
Regulation Name: Antimicrobial Susceptibility Test System – Short Incubation
Regulatory Class: II
Product Code: LON
Dated: November 14, 2008
Received: November 17, 2008

Dear Ms. Tenllado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083383

Device Name: VITEK® 2 Gram Positive Erythromycin (≤ 0.25 – ≥ 1 µg/ml)

Indications For Use:

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 and VITEK® 2 Compact Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae*, and *S. pneumoniae*.

VITEK® 2 Gram Positive Erythromycin for *Streptococcus pneumoniae* is designed for antimicrobial susceptibility testing of Gram positive *Streptococcus pneumoniae* and is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. VITEK 2 Gram Positive Erythromycin for *Streptococcus pneumoniae* is a qualitative test.

This submission is for the addition of an intermediate interpretive criteria.

Erythromcyin has been shown to be active against the microorganisms listed below according to the FDA label for the antimicrobial.

Active *in vitro* and in clinical infections:
Streptococcus pneumoniae

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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